Drug manufacturers in the country

1872. SHRI LALITBHAI MEHTA:

SHRIMATI SAVITA SHARDA:

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

(a) the number of Drug manufacturers working in the country, State-wise;

(b) the quantum of production of Drugs by the Manufacturers, in Monetary terms, State-wise;

(c) whether it is a fact that nearly Rs. 4000 crores worth of duplicate drugs are manufactured by unregistered Drug Manufacturers in the country; and

(d) the steps Government propose to combat duplicate drug manufacturing causing danger to the life of citizens of our country?

THE MINISTER OF CHEMICALS AND FERTILIZERS (SHRI RAM VILAS PASWAN): (a) and (b) A large number of units manufacturing drugs and related items, both in the organised sector and in the small scale sector are operating in the country. However, as per the information available with the Office of the Drugs Controller General of India, the details of Drug manufacturers working in the country, State-wise and in force as on November, 2003 is enclosed as Statement-I (*See* below). Under the provisions of the Drugs and Cosmetics Act, 1940 and Rules thereunder, the responsibility for regulating manufacture and sale of drugs including monitoring their quality is primarily vested with the State Governments.

(c) Being a clandestine activity, it is difficult to assess the actual quantum of spurious drugs. However, as per the information available from the State Drug Controllers, 38824, 43138 and 40862 drugs samples were tested during the peirod 2001-02, 2002-03 and 2003-04 out of which 96, 129 and 118 samples respectively were found spurious which is 0.33 per cent, 0.29 per cent and 0.28 per cent of the samples reported spurious.

(d) Steps taken by the Government of India to check the menace of Spurious Drugs is indicated in the attached Statement-II.

Statement-I

Categorywise No. of manufacturing licenses in States

Sl. No.	States	Bulk Drugs	For-mula-tion	Large Vol. Paren-ter	Vac-cines	Blood Banks	Surgi-cal Dress-ings	Disin-fec-tants	Repac-king	Loan Licen-se	Medi-cal Devi-ces	Cos-metics	Ayur-vedic, Unani Siddha	Homeo-pathic	Miscel-lane-ous not cov-ered
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
1.	Andhra Pradesh	200	416	5	14	179	21		27	620		59			31
2.	Assam	2	19	2		51	15	12	3		1	10	38	1	6
3.	Arunachal Pradesh		2			3									
4.	Bihar		236	3	1	38		included	in 236	7		7	240	26	2
5.	Chandigarh	1	13			3		4				2	3		
6.	Chhattisgarh	2	37			1	7	7		2	4	5	44	2	
7.	Dadra and Nagar Haveli	5	56					1	2	47		54	15		
8.	Delhi	4	90		1	42	28	4	1	89	1	499		69	
9.	Goa	5	88	2		7	1	1	2	186	1	16	6		
10.	Gujarat	430	526	18	6	159	52	19	15	644	117	324	930	11	
11.	Haryana	23	230	6	2	42	65	8	6	13	4	39		10	
12.	Jammu & Kashmir	3	15		1	14	5	2			1	1	10		
13.	Karnataka	57	84	2	2	135	21	32	9	291	3	74			33
14.	Kerala	4	60	10	1	125	2	2	6	15	4	11	800	17	
15.	Maharashtra	347	693	17	9	245	38	29	49	1931	19	513	655	25	68

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
16.	Madhya Pradesh	54	435	12	1	101	44	20	43	263	4	54	539	17	15
17.	Meghalaya		2		1	4						3			
18.	Mizoram		1			5	1								
19.	Orissa	4	43		2	63	19	30	31	14		39		25	6
20.	Pondicherry	7	34			8		3	3	12	3	52	51	7	2
21.	Punjab	9	187	3	2	72	13			12		71		3	13
22.	Rajasthan	19	85	2	1	60	48	10	9	68	5	24		4	31
23.	Sikkim		1			3						3	1	1	
24.	Tamil Nadu	62	436	15	5	192	103	21	20	325	12	175	531	7	58
25.	Tripura		4			6	1						1		
26.	Uttaranchal	10	8	1	1	18	7	1	1	6	1	3		1	
27.	Uttar Pradesh	44	329	9	3	126	115	30	53	16	12	51		40	12
28.	West Bengal	46	280	27	3	104	32	30	40	131	7	181	850	700	10
	TOTAL:	1338	4410	134	56	1806	638	273	320	4692	199	2282	4714	966	287

Statement-II

Initiatives taken by the Govt. of India to tackle the problem of spurious drugs

(i) Specific definition of spurious drugs and cosmetics introduced in 1982.

(ii) Enhanced penal provisions upto life imprisonment provided under Sec. 27, amended in 1982.

(iii) Guidelines for focused strategies to check manufacture and distribution of spurious drugs circulated to all Drug Control Authorities.

(iv) Issues concerning alleged sale of spurious drugs taken up by Union Health Minister with State Health Ministers in conference of Central Council of Health and Family Welfare.

(v) Financial assistance provided to States for augmentation of drug testing facilities.

(vi) Matter concerning sale of spurious drugs and initiatives required to be taken by States was taken up by Union Health Minister with all Chief Ministers in October, 2002.

(vii) Report of the DGHS Committee on spurious drugs circulated to all State Drugs Controllers with a request to implement the recommendations.

(viii) World Bank assisted Capacity Building Project for augmenting drug testing facilities and training of drug regulatory, quality control officials and industry personnel has been commissioned.

(ix) Annual testing capacity to be raised to 1,00,000 samples as against 36,000 to 38,000 samples.

(x) Special training programme on investigation and legal skills organized for State officials.

(xi) Expert Committee under Dr. Mashelkar set up in January, 2003 to examine the extent of problem of spurious drugs in the

country. The Cabinet accorded approval for the introduction of Drugs and Cosmetics (Amendment) Bill, 2005, incorporating recommendations of the Committee, in the Parliament subject to certain modifications, namely, replacing capital punishment to life imprisonment and increasing the quantum of fines.

Drug Testing Laboratories

†1873. SHRI DILIP SINGH JUDEV: Will the MINISTER OF HEALTH AND FAMILY WELFARE be pleased to state:

(a) the number of laboratories to test the quality of medicines in the country alongwith the locations thereof;

(b) the names and number of samples of medicines tested in these laboratories during the last three years and the number and names of medicines found to be adulterated and sub-standard;

(c) the action taken against manufacturers of medicines; and

(d) the details of facilities available for testing quality of medicines being sold in the States, not having laboratories?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRIMATI PANABAKA LAKSHMI): (a) A list of Government Drug Testing Laboratories to test the quality of medicines in the country along with the locations is enclosed as Statement, (*See* below).

(b) As per the feedback available from the States details are given below:

Year	Number of samples Tested	Number of samples declared sub-standard	Number of samples declared Spurious
2001-2002	38,825	3458	96
2002-2003	43,138	3724	129
2003-2004	40,862	3499	118

†Original notice of the question was received in Hindi.